Remarks

Applicants acknowledge and appreciate both the allowance of claims 3-7, 11, 14, 49, 52, and 56, and the indication of allowable subject matter in claims 13 and 26.

Rejection Under 35 U.S.C. § 103

Claims 1, 2, 8, 10, 12, 15, 16, 18, 19, 21, 23, 24, 43-47, 50, 51, and 53-55 remain rejected under 35 U.S.C. § 103(a) as obvious over WO 97/34697. For convenience, U.S. Patent No. 6,114,658 to Roth et al. (hereinafter "Roth") shall be referenced herein and considered an English-language equivalent of WO 97/34697. The rejection is respectfully traversed.

Roth discloses that it is desirable to encapsulate sensitive materials, such as chemical indicator materials, catalysts, and pharmaceuticals (col. 1, lines 9-10). Roth teaches that conventional methods for encapsulating such sensitive materials include "encapsulation of the substance in a glass bulb, plastic foils or similar packings" (col. 1, lines 20-22).

In the last Office Action, the Examiner contends that pharmaceuticals "are only encapsulated in miniaturized devices for one reason, being placed in the body." This statement is inaccurate, unsupported by any objective evidence, and ignores evidence to the contrary found in the prior art and background of Roth.

While the ultimate use of a pharmaceutical, as noted by the Examiner, is indeed its therapeutic administration to a human or animal body, it does not follow that all devices for containing pharmaceuticals are to be implanted. On the contrary, a variety of storage and testing containment devices are never intended for implantation into a body. A pharmaceutical compound can be "encapsulated" for a variety of reasons and in a variety of types and sizes of

vessels over its useful life as it is manufactured, tested, packaged for bulk transport and storage, packaged in unit dosage forms, and finally readied for administration.

For instance, Roth teaches that pharmaceuticals are conventionally contained in a "glass bulb, plastic foils, or similar packings." This undoubtedly indicates that a pharmaceutical can be encapsulated or packaged using devices and materials unsuitable for implantation. A glass-bulb loaded with a pharmaceutical clearly would not be suitable for implantation into a patient.

The Examiner seems to allege that merely because Roth's devices are "miniaturized" they necessarily must be for implantation. This is untrue and evidences improper hindsight reconstruction at its worst. Roth simply teaches that "due to the high miniaturization possibilities offered by the present method, the size of the [device]whole array can be kept very small." Furthermore, the Examiner's allegation improperly ignores the background art in Roth, where DE 3919042 is discussed. This patent describes

> **micromechanical structures** with reservoirs used to test substances for possible changes in physical and/or chemical properties. ... The structure comprises a block and a cover.... The block has a number of depressions of particular size shape, distribution, etc., and the cover has elevations which match these exactly so as to provide a hermetic closure...**These structures are used** for evaluation and documentation in biotechnology, genetic engineering, cell or immune research, or **for other medical ... research. They allow dangerous substances to be stored and handled (for testing, etc.) safely, and provide simple process control and evaluation of tests on very small amounts of sample.**

(Abstract of DE 2919042)

Thus, it is abundantly clear that one skilled in the art would understand Roth as disclosing the encapsulation of a pharmaceutical into a miniaturized device only for the purpose of storage and

in vitro testing of small samples of a potential pharmaceutical compound, such as in a drug discovery screening process.

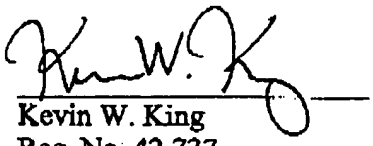
The Examiner also argues that "whether Roth is merely testing the *device* or not, one of ordinary skill would have found it obvious to implant the encapsulated drug device." This statement indicates that the Examiner failed to appreciate the essential point of applicants' prior response. As should now be clear (from the preceding paragraphs), applicants do **not** argue that Roth is testing implantable devices *in vitro*. Rather, what applicants have tried to convey is that Roth discloses encapsulating a pharmaceutical in a miniaturized device for the ultimate purpose of *in vitro* testing of the pharmaceutical compounds or other sensitive materials contained in the devices.

In summary, nothing in Roth provides any motivation to modify its device to achieve an implantable device for drug delivery as claimed by the present applicants. One can conclude only that the Examiner's rejection is improperly based on hindsight reconstruction in view of applicants' specification, since the reasoning put forth by the Examiner in support of the rejection is flawed, unsupported, and contrary to the teachings of the prior art described in the sole reference being relied upon.

Accordingly, the Patent Office not met its burden, and no proper *prima facie* case of

obviousness has been established. Allowance of claims 1-8, 10-16, 18, 19, 21, 23, 24, 26, 43-47, and 49-56 is therefore earnestly solicited.

Respectfully submitted,



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